

**OTODINE- chlorhexidine gluconate liquid**  
**Nextmune AB**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, [click here](#).*

-----  
**Otodine™**

Ear cleaning chlorhexidine digluconate solution to remove excess ear wax in dogs and cats

**Active Ingredient(s):**

Chlorhexidine digluconate 0.15%.

**Inactive Ingredient(s):**

1,2-Hexanediol; Caprylyl Glycol, deionized water; erythritol; octane-1,2-diol; propanediol; Tris-EDTA.

**Indications:** For cleaning and removal of excess cerumen (ear wax) in dogs and cats.

**Properties:** The active ingredient(s) in Otodine™ provide an effective cleansing action which helps to remove excess ear wax.

**Directions for use:**

Flood the ear canal with the cleaning solution. Gently massage the ear canal to break up wax and debris. Using a cotton ball, remove any excess solution left in the ear. Otodine may be used 1 to 2 times a day. The solution will also clean the ear flap and surrounding skin of the ear. Do not rinse.

**Precautionary statements:**

For use in the ears of dogs and cats only. May cause eye irritation. Consult a veterinarian before using on pregnant, lactating or breeding animals; puppies; kittens; or animals with a pre-existing medical condition. Use with caution in older animals. If an animal has an adverse reaction to treatment, discontinue use and contact your veterinarian.

**Storage:** Store at room temperature. Do not freeze.

**Warning:** Keep out of reach of children.



**Distributor:**

**Nextmune US, LLC**

2801 S. 35th St.,  
Phoenix, AZ 85034  
480-464-8971

**Made**

in **Spain**

**Manufacturer:**

**I.C.F. Srl**

via G.B. Benzoni, 50  
26020 Palazzo Pignano (CR) - Italy  
Tel +39 0373 982024  
Fax +39 0373 982025

**customer@icfsrl.it**

**www.icfpet.com**

**iCF™**

**Evolution of  
Knowledge**

PRINCIPAL DISPLAY PANEL - 100 ml Bottle Carton

Otodine™  
Ear  
cleaning  
Chlorhexidine digluconate  
solution to remove  
excess ear wax  
in cats and dogs  
Developed in Italy  
iCF™  
3.38 fl. oz.(100 ml)

OTODINE				
chlorhexidine gluconate liquid				
Product Information				
Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:86127-009	
Route of Administration	AURICULAR (OTIC)			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4KO0DY52L)		CHLORHEXIDINE GLUCONATE	1.5 mg in 1 mL	
Inactive Ingredients				
Ingredient Name		Strength		
water (UNII: 059QF0K00R)				
erythritol (UNII: RA96B954X6)				
propanediol (UNII: 5965N8W85T)				
Tromethamine (UNII: 023C2WHX2V)				
Edetate Sodium (UNII: MP1J8420LU)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:86127-009-03	1 in 1 CARTON		
1		100 mL in 1 BOTTLE, PLASTIC		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER			01/01/2021	

Labeler - Nextmune AB (352950223)

Establishment

Name	Address	ID/FEI	Business Operations
ICF SRL		432862407	MANUFACTURE

Establishment			
Name	Address	ID/FEI	Business Operations
Medichem SA		464043381	API MANUFACTURE